

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 18, 2022

Findings Date: May 18, 2022

Project Analyst: Donna Donihi

Co-Signer: Mike McKillip

Project ID #: F-12195-22

Facility: Hickory Ridge Dialysis Center

FID #: 160494

County: Cabarrus

Applicant: Total Renal Care of North Carolina LLC

Project: Add no more than five in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 in-center stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Total Renal Care of North Carolina LLC (hereinafter referred to as the applicant “ or Hickory Ridge Dialysis) proposes to add no more than five in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 in-center dialysis stations upon project completion.

Need Determination (Condition 1)

Chapter 9 of the 2022 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9B, page 135, the county need methodology shows there is not a county need determination for additional dialysis stations in Cabarrus County.

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However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 1 of the facility need methodology in the 2022 SMFP if the facility is a “new,” “small,” or “new and small” facility as defined in the 2022 SMFP, and if the facility’s current reported utilization is at least 75 percent, or 3.0 patients per station in a given week. “Current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted. If applying pursuant to Condition 1, the facility may only apply once during the calendar year.

In Section B, page 19, the applicant reports the following:

Facility Need Methodology Condition 1 (New and Small Facilities Only)	Response
Number of months the facility had been certified as of the data cut-off date in the SMFP	25
Number of stations in the facility as of the data cut-off date in the SMFP	10
According to Table 9A in the 2022 SMFP, the facility is designated as new, small, or new and small	small
Number of stations proposed in this application	5
Number of in-center patients per station as of the current reporting date	3.0
Current Reporting Date (no more than 90 days before the application is submitted)	1/31/2022
Previous Reporting Date (six months prior to the Current Reporting Date)	7/30/2021

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of five additional stations are needed at this facility, as illustrated in the following table.

1	# of In-center Patients as of the Current Reporting Date	30
2	# of In-Center Patients as of the Previous Reporting Date	23
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	7
4	Divide Line 3 by Line 2 (6-month Growth Rate)	0.3
5	Multiply Line 4 by 2 (Annual Growth Rate)	0.6
6	Multiply Line 5 by Line 1 (New Patients)	18.3
7	Add Line 6 to Line 1 (Total Patients)	48.3
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	17.2
9	# of Stations as of the Application Deadline	10.0
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	7.2

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 7, based on rounding allowed in Condition 1.b.(vii). Condition 1.c of the facility need methodology states, “*The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.*” The applicant proposes to add 5 new stations; therefore, the application is consistent with Condition 1 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2022 SMFP which is applicable to this review Policy GEN-3: Basic Principles.

Policy GEN-3, on page 30 of the 2022 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 20-21; Section N, page 76; Section O, pages 79-81, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B, page 21-22; Section C, page 30; Section L, pages 68-72; Sections N, page 76, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, pages 20; Section N.2, page 76; Section Q; and referenced exhibits. The information provided by the applicant regarding its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal would maximize healthcare value.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2022 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN -3 based on how it describes the facility's policies and programs, which promote the concepts of quality, equitable access and maximum value for resources.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than five in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 in-center dialysis stations upon project completion.

In section A.5, page 15, the applicant provides the following table.

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Hickory Ridge Dialysis

# OF STATIONS	DESCRIPTION	PROJECT ID #
10	Total # of existing certified stations as reported in the SMFP in effect on the day the review will begin	
5	# of stations to be added as part of this project	F-12195-22
0	# of stations to be deleted as part of this project	
0	# of stations previously approved to be added but not yet certified	
0	# of stations previously approved to be deleted but not yet certified	
0	# of stations proposed to be added in an application still under review	
0	# of stations proposed to be deleted in an application still under review	
15	Total # of stations upon completion of all facility projects	

As illustrated in the table above, the applicant proposes to add five dialysis stations for a total of 15 stations upon project completion.

Patient Origin

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area is Cabarrus County. Facilities may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 25 and 26, the applicant provides the in-center (IC) patient origin for Hickory Ridge Dialysis during the last full operating year, January 1, 2021 – December 31, 2021 (CY 2020), and the projected patient origin for the second full operating year following project completion, January 1, 2024 - December 31, 2024 (CY 2024), as summarized in the following tables. The facility does not presently serve home training patients and does not propose to develop those services as part of this project.

County	Hickory Ridge Dialysis Patient Origin 01/01/2021 to 12/31/2021	
	Patients	% of Total
Cabarrus	11	37.9%
Mecklenburg	17	58.6%
Virginia	1	3.4%
Total	29	100.0%

Source: Section C.2, page 25.

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County	Projected Patient Origin In-Center Patients	
	01/01/2025-12/31/2025	
	Patients	% of Total
Cabarrus	29.7256	62.3%
Mecklenburg	17	35.6%
Virginia	1	2.1%
Total	47.7256	100.0%

Source: Section C.3, page 26.

In Section C, pages 25-26 and Section Q, Form C, the applicant provides the assumptions and methodology used to project IC patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin at Hickory Ridge Dialysis based on its historic patient origin as of January 31, 2022.
- The applicant projects in-center patient census for residents of Cabarrus County will increase by 26 % per year, which is less than the historical growth rate for the facility.
- The applicant does not project any growth in patient census for patients residing outside Cabarrus County.

Analysis of Need

In Section C, page 28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 28, the applicant states:

“Pursuant to Condition 1 of the Facility Need Methodology, there is a facility need determination of 7 stations for Hickory Ridge Dialysis, which had 10 existing stations, as reported in Tables 9A of the 2022 SMFP. In Section C, Question 3 we demonstrate that an additional 5 stations will be well utilized by the population to be served, the current and projected in-center patients of Hickory Ridge Dialysis. The addition of stations serves to increase capacity and proactively address the issues of growth and access at the facility. Dialysis patients spend a significant amount of time in their facilities preparing for and receiving treatment -- three times a week for in-center patients. The additional stations provide opportunities to open appointment times on the more desirable first shift.”

The information is reasonable and adequately supported for the following reasons:

- Based on application of condition 1 of the facility need methodology in the 2022 SMFP, the applicant demonstrates the need for up to seven additional stations at Hickory Ridge Dialysis.

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- The applicant provides supporting documentation in its projected utilization based on the historical growth in utilization at Hickory Ridge Dialysis since it became operational in August 2019.

Projected Utilization

In Section C, page 27 and Section Q, Form C, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table.

Hickory Ridge Dialysis Center In-Center Patients

	In-Center Stations	In-Center Patients
The applicant begins with the 30 patients dialyzing on 10 stations at the facility as of 1/31/2022.	10	30
Cabarrus County patient census is projected forward 11 months to 12/31/2022 and is increased by 11/12 of the projected growth rate, 26.0%.		$12 \times 1.238 = 14.86$
The 18 patients from outside Cabarrus County are added to the facility's census. This is the ending census for the first full interim year.		$14.86 + 18 = 32.86$
Cabarrus County patient census is projected forward a year to 12/31/2023 and is increased by 26.0%.		$32.86 \times 1.26 = 41.40$
The 18 patients from outside Cabarrus County are added to the facility's census. This is the ending census for the second full interim year.		$41.40 + 18 = 59.40$
The proposed project is projected to be certified on 01/01/2024. This is the station count at the beginning of the project's first full fiscal year (FY1). The facility's Cabarrus County patient census is projected forward a year to 12/31/2024 and is increased by 26.0%.	$10 + 5 = 15$	$59.40 \times 1.26 = 74.84$
The 18 patients from outside Cabarrus County are added to the facility's census. This is the ending census for FY1.		$74.84 + 18 = 92.84$
The facility's Cabarrus County patient census is projected forward a year to 12/31/2025 and is increased by 26.0%.		$92.84 \times 1.26 = 116.98$
The 18 patients from outside Cabarrus County are added to the facility's census. This is the ending census as of the project's second full fiscal year (FY2).		$116.98 + 18 = 134.98$

Source: Table in Section Q., page 88.

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At the end of FY1 (CY2024) the facility is projected to serve 42 in-center patients and at the end of FY2 (CY2025) the facility is projected to serve 48 in-center patients. The projected utilization rates for the first two operating years are as follows:

- By the end of FY1 Hickory Ridge Dialysis is projected to have:
42 patients / 15 certified stations = 2.80 patients / station
 $2.80 / 4 = .70$ or 70.0% utilization rate
- By the end of FY2, Hickory Ridge Dialysis is projected to have:
48 patients / 15 certified stations = 3.20 patients / station
 $3.20 / 4 = .800$ or 80.0% utilization rate.

The projected utilization exceeds the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C.2203 (b)

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant projects future utilization based on historical utilization at Hickory Ridge Center by basing the projections on the actual patient population as of January 31, 2022
- The applicant projects the Cabarrus County patient census will increase by an average annual rate of 26% through the second operating year of the project, which is less than the average annual rate of growth at the facility from 2019 to 2021, which was 66%.
- The applicant does not project growth in patient census for its patients who do not reside in Cabarrus County.

Access

In Section C.6, pages 30-31, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

We will make every reasonable effort to accommodate all patients, especially those with special needs such as the handicapped, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

Hickory Ridge Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

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On page 32, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second year of operation following completion of the project, as summarized in the following table

	Estimated Percentage of Patients by Group
Low Income Persons	82.8%
Racial and Ethnic Minorities	75.9%
Women	41.4%
Persons with Disabilities	100%
Elderly	55.2%
Medicare Beneficiaries	75.9%
Medicaid Recipients	6.9%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant currently serves the needs of medically underserved groups that utilize ESRD services and provides evidence that it will continue to do so.
- The applicant has policies in place to prevent discrimination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to add no more than five in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 in-center dialysis stations upon project completion.

In Section E, page 41, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status quo*-The applicant states that this alternative was dismissed due to the growth rate at the facility.
- *Relocate Stations from Another DaVita Facility*- The applicant states that of the four DaVita facilities in Cabarrus County, two are operating at less than 75% capacity. The application states relocating stations from Harrisburg Dialysis Center would negatively impact the facility's operations and the patients presently served by this facility as it would disrupt patient and teammate scheduling at the facility. Cannon Dialysis opened in December 2020 and relocating stations for the proposed project would reduce the number of stations to below 10 at this new/small facility.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC (hereinafter the certificate holder) shall materially comply with all representations made in the certificate of need application.**

2. Pursuant to condition 1 of the facility need determination in the 2022 SMFP, the certificate holder shall develop no more than five additional in-center dialysis stations for a total of no more than 15 in-center dialysis stations at Hickory Ridge Dialysis upon project completion.
 3. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
 4. Progress Reports:
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on October 1, 2022
 5. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than five in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 in-center dialysis stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

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Form F.1a Capital Cost	Applicant 1
	Total Renal Care of North Carolina, LLC
Medical Equipment	\$14,000
Non-Medical Equipment	\$17,779
Furniture	\$9,000
Total Capital Cost	\$40,779

In Section Q, page 92, the applicant provides the assumptions used to project the capital cost.

In Section F, page 32, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project since it is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 43, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DaVita, Inc.	Total
Loans	\$	\$
Accumulated reserves or OE *	\$40,779	\$40,779
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$40,779	\$40,779

* OE = Owner's Equity

Exhibit F contains a letter, dated February 23, 2022, from the Chief Accounting Office for DaVita, Inc., parent company to Total Renal Care of North Carolina LLC, authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F also contains the Consolidated Balance Sheets from DaVita, Inc., for the year ending December 31, 2021, showing that DaVita, Inc. has sufficient assets to fund the capital cost of the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that

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revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

	1 st Full Fiscal Year	2 nd Full Fiscal Year
Total Billable Treatments	5803	6618
Total Gross Revenues (Charges)	\$2,280,644	\$2,601,036
Total Net Revenue	\$2,179,577	\$2,485,771
Average Net Revenue per treatment	\$393	\$393
Total Operating Expenses (Costs)	\$1,971,835	\$2,125,164
Average Operating Expense per treatment	340	321
Net Income	\$207,742	\$360,607

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of funds for the capital needs of the proposal.
 - The applicant adequately demonstrates funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than five in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 in-center dialysis stations upon project completion.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located. Each county comprises a service area except for two*”

multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area is Cabarrus County. Facilities may serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Cabarrus County as of December 31, 2020. The applicant owns and operates four dialysis facilities in Cabarrus County. The applicant is the only provider of dialysis services in Cabarrus County.

Cabarrus County Dialysis Facilities

Facility Name	Certified Stations as of 12/31/2020	# of In-center Patients as of 12/31/2020	Utilization by Percent as of 12/31/2020
Cannon Dialysis	11	8	18.18%
Copperfield Dialysis	27	88	81.48%
Harrisburg Dialysis Center	28	77	68.75%
Hickory Ridge Dialysis	10	27	67.50%

Source: SMFP 2022, Table 9A

In Section G, page 50, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Cabarrus County. The applicant states:

“While adding stations at this facility does increase the number of stations in Cabarrus County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant’s proposal to add dialysis stations is based on the facility need methodology.
- The applicant adequately demonstrates that the proposed addition of five stations is needed in addition to the existing and approved stations in Cabarrus County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to add no more than five in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 in-center dialysis stations upon project completion.

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 2/28/2022	2nd Full Operating Year CY 2025
Administrator	1.00	1.00
Registered Nurse (RNs)	1.25	2.00
Technicians (PCT)	3.75	5.75
Dietician	0.50	0.50
Social Worker	0.50	0.50
Administration/Business Office	0.50	1.00
Other: Biomedical Tech	0.50	0.50
TOTAL	8.00	11.25

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form H Staffing, which is found in Section Q. In Section H.2 and H.3, pages 53 and 54, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

- The applicant projects an increase in the FTE staffing positions necessary to accommodate the proposed increase in healthcare services at Hickory Ridge Dialysis.
- The increased costs of annual salary increases are accounted for in the budgeted operating costs.
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise plan for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to add no more than five in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 in-center dialysis stations upon project completion.

Ancillary and Support Services

In a table in Section I, page 56, the applicant identifies the ancillary and support services are necessary for the proposed services. On pages 56- 59 the applicant explains how each ancillary and support service is made available.

The applicant adequately demonstrates the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides dialysis services at Hickory Ridge Dialysis.
- The applicant describes how it provides these services at the existing facility

Coordination

In Section I, page 59, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I. The applicant adequately demonstrates the proposed services will be coordinated with the existing health care system based on the following:

- The applicant has numerous years of experience serving the needs of dialysis patients in Cabarrus County.
- The applicant has established relationships with community health care and ancillary service providers where dialysis patients can receive appropriate referrals for necessary services related to their condition.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing

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the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant states there is no construction or renovation associated with the proposed project. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 68, the applicant provides the historical payor mix during last full operating year (CY 2021) the proposed services, as shown in the table below.

Hickory Ridge Dialysis Historical Payor Mix CY 2021		
Payor Source	In-Center Dialysis	
	# of Patients	% of Total Patients
Insurance*	4	13.8%
Medicare*	22	75.9%
Medicaid*	2	6.9%
Other: Misc. Incl. VA	1	3.4%
Total	29	100.0%

*Including managed care plans

In Section L, page 69, the applicant provides the following comparison.

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Hickory Ridge Dialysis	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area*
Female	41.0%	51.2%
Male	58.6%	48.8%
Unknown	0.0%	0.0%
64 and Younger	44.8%	86.6%
65 and Older	55.2%	13.4%
American Indian	0.0%	0.7%
Asian	3.4%	4.7%
Black or African - American	62.1%	19.6%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	24.1%	72.4%
Other Race	6.9%	2.4%
Declined / Unavailable	0.0%	0.0%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 70, the applicant states that the facility is not obligated under any applicable federal obligations to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 70, the applicant states that during the last 18 months years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

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- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 71, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Hickory Ridge Dialysis Projected Payor Mix CY 2025		
	In-Center Dialysis	
Payor Source	# of Patients	% of Total Patients
Insurance*	6.58	13.8%
Medicare*	36.21	75.9%
Medicaid*	3.29	6.9%
Other: Misc. Incl. VA	1.65	3.4%
Total	47.73	100.0%

* Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 75.9% of in-center dialysis services will be provided to Medicare patients and 6.9% to Medicaid patients.

On page 71, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projections are based on the historical (CY 2021) payor mix at Hickory Ridge Dialysis.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by staff, and admission by personal physicians.

C

In Section L, pages 72, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 74, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

- Hickory Ridge Dialysis has offered the facility as a clinical learning site for nursing students from Rowan-Cabarrus County Community College.
- See Exhibit M.1 for a copy of the letter sent to Rowan-Cabarrus County Community College.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than five in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 in-center dialysis stations upon project completion.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area is Cabarrus County. Facilities may serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Cabarrus County as of December 31, 2020. The applicant owns and operates four dialysis facilities in Cabarrus County. The applicant is the only provider of dialysis services in Cabarrus County.

Cabarrus County Dialysis Facilities

Facility Name	Certified Stations as of 12/31/2020	# of In-center Patients as of 12/31/2020	Utilization by Percent as of 12/31/2020
Cannon Dialysis	11	8	18.18%
Copperfield Dialysis	27	88	81.48%
Harrisburg Dialysis Center	28	77	68.75%
Hickory Ridge Dialysis	10	27	67.50%

Source: 2022 SMFP, Table 9A.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 76, the applicant states:

“The expansion of Hickory Ridge Dialysis will have no effect on competition in Cabarrus County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.”

Regarding the impact of the proposal on cost effectiveness, quality, access by medically underserved groups in Section N, page 76, the applicant states:

“The expansion of Hickory Ridge Dialysis will enhance accessibility to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services. As noted in Form H, with additional capacity, greater operational efficiency is possible which positively impacts cost-effectiveness. As discussed in Section B and Section O, DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all its patients. As discussed in Section C, Question 6, and documented in Exhibit L.5, the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate all of its patients.”

See also Sections B, C, F, L, O, and Q of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality and access because the applicant adequately demonstrates that:

1. The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable. Cost-effectiveness.
2. Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
3. Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form O, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 106 of this type of facility located in North Carolina.

In Section O, page 81, the applicant states that, during the 18-month look-back period, none of the facilities owned by North Carolina entities of the parent company, DaVita, was determined to have had an incident related to quality of care that resulted in a finding of immediate jeopardy. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

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(b) An applicant proposing to increase the number of dialysis stations in:

(1) an existing dialysis facility; or

(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C-

In Section C, page 27 the applicant projects Hickory Ridge Dialysis will serve 42 patients on 15 stations. (42 patients / 15 certified stations = 2.80 in-center patients / station) as of the end of the first full operating year (CY2024) following project completion. This meets the minimum performance standard requirement of 2.8 patients per station per week. The discussion regularly projected utilization found in criteria (3) is incorporated herein by references.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C-

In Section C, pages 26-27, and Section Q, Form C, the applicant provides the assumptions and methodology it uses to project utilization of the facility.